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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,483	01/10/2001	Yoshiyuki Matsumoto	Q62437	2611

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/743,483

Applicant(s)

MATSUMOTO ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____                                     |

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1. Claims 1-11, 13, 15, 16, 17 are pending. Claims 12, 14 have been canceled according to the amendment filed on 12-17-2001.
2. The check for the Notice of draftsperson's patent drawing review on the PTO-326 was an error. It was meant for the IDS.

***Claim Rejections - 35 USC § 112(2)***

3. The rejection under second paragraph of 35 U.S.C. 112 for claims 1-15 set forth in the previous office action is withdrawn because the amendment has obviated the rejection.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 13 is dependent on the canceled claim 12 and is dependent on itself
- b. Method claims 16, 17, the subject to whom the composition is administered is missing but required. What is a 'biologically effective amount'?
- c. Claims 13, 15-17,
  - What are the conditions wherein a disease is prevented *and/or* treated?
  - What is intended for a 'disease of the respiratory organs, a disease of the circulatory organs, a disease of bone/cartilage metabolism'?

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 13, 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the amended claims, in the proviso, the specific compound wherein  $m=0$ , A is an alkylene, J represents 2, 5-dimethylimidazole-4-yl,  $G = -CH_2-$ , the specific compound wherein J is alkylene, A is a pyrimidine ring and the position of the pyrimidine ring binds to the methylene adjacent to the S in formula (1) and the specific compound wherein  $m=1$  or 2, J represents 2, 5-dimethylimidazole-4-yl,  $G = -CH_2-$  or J is alkylene, A is a pyrimidine ring and the position of the pyrimidine ring binds to the methylene adjacent to the S in formula (1), are not described in the specification. The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir.1996).

### *Duplicate claims*

6. The advisory that should claims 1-11 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof and the advisory that should claim 13 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof are rendered moot by the cancellation of claims 12, 14.

### *Claim Rejections - 35 USC § 103*

7. The 103 rejection over Bru-Magniez I (5021443, PTO-1449), or Bru-Magniez II (5124336, PTO-1449, CIP of 5021443) or Bru-Magniez III (51228359, PTO-1449, CIP of

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5021443). The reference to Bru-Magniez I is applicable to Bru-Magniez II or III is maintained for reasons of record. The rejection is applicable to new claims 16-17.

Applicant argues that Bru-Magniez teaches the inventive compounds as thromboxane receptor antagonists and does not teach these compounds as chymase inhibitors as in the instant. The court, however, has held that "it is not necessary in order to establish a prima facie case of obviousness....that there be a suggestion or expectation from the prior art that the claimed [invention] will have the same or similar utility as one newly discovered by the applicant" and concluded that a prima facie case was established because 'the art provided the motivation to make the claimed composition in the expectation that they would have similar properties'. In re Dillon, 919 F2d. 688, 16 USPQ 2d. 1897.

Furthermore, Bru-Magniez teaches the use of these compounds for treating myocardial infraction, pulmonary embolism, pneumonia, circulatory shock etc. (column 1, lines 25-30), which are diseases 'of the respiratory organs' or 'of the circulatory organs' as recited in the instant claim 17. The administration of the same compounds to the patients suffering from the same diseases would inherently inhibit the chymase as in the instant.

8. The 35 U.S.C. 103(a) rejection over JP 1265089 (PTO-1449) is maintained for reasons of record since the amendment to proviso out the compound of JP 1265089 is new matter.

Amending the claims to set a demarcation from the prior art compound with support from the specification would obviate the rejection.

9. The 35 U.S.C. 103(a) rejection over Shimamura (JP 05112559) is maintained for reasons of record since the amendment to proviso out the compound of Shimamura is new matter.

Amending the claims to set a demarcation from the prior art compound with support from the specification would obviate the rejection.

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*Conclusion*

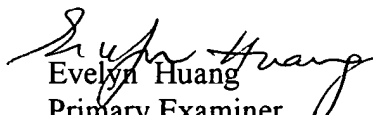
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on 703-308-2439. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

January 14, 2002